UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,498	10/11/2005	Taliesin John Golesworthy	4393-120 US	5329

26817 7590 08/04/2009
MATHEWS, SHEPHERD, MCKAY, & BRUNEAU, P.A.
29 THANET ROAD, SUITE 201
PRINCETON, NJ 08540

EXAMINER	
NGUYEN, TUAN VAN	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,498	GOLESWORTHY ET AL.	
	Examiner	Art Unit	
	TUAN V. NGUYEN	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,20-22,24-32 and 34-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1-14,20-22,24-32 and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In previous Office action, claims 1-14, 20-22, 24-32, 34, 35 and 36-37 were examined and rejected, claim 38 withdrawn from consideration as being directed a non-elected invention and claim 33 was indicated allowable over prior art of record.
2. This Office action is in response to the RCE filed on May 18, 2009.

Continued Examination Under 37 CFR 1.114

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18, 2009 has been entered.

Response to Amendment

4. According to the submission, claim 38 has been canceled. Accordingly, claims 1-14, 20-22, 24-32, 33, 34, 35 and 36-37 are pending in this present application and they are presented for examination.
5. Claims 32, 34, 35 and 37 have been amended to overcome the objection, therefore, the objection in previous Office action is hereby withdrawn.

6. Applicant's arguments with respect to the rejection of claims 1-12, 4-10, 20-22, and 24, 26-31 and 36 under 35 USC § 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of D'Urso (US 6,112,109) have been fully considered but they are not persuasive.

   a. Applicant argues that (see pages 8 and 9 of the Remarks) Sirhan et al. teach (col. 1, lines 19-31) against treatment using a prostheses because it "causes considerable trauma, results in high mortality and morbidity and, even when completely successful, required a lengthy recuperation period" while D'Urso does not teach or suggest the a stent being customized to a patient and pre-formed having a sized and shape which morpholocially matches the morphological profile and contour of the ascending aorta, accordingly, one of ordinary skill in the art would not look to D'Urso for combination with Sirhan et al. because Sirhan et al. teach away from the teaching of D'Urso is incorrect. By definition, prostheses is defined as an artificial device to replace or augment a missing or impaired part of the body. The prosthetic graft as disclosed in the Background of The Invention and the invention of Sirhan et al. is a prosthesis to augment an impaired part of the body. Noting that nowhere in column 1, lines 19-31 does Sirhan teach against of using prosthesis graft. In column 1, lines 19-31, Sirhan discloses the trauma that cause by the surgical procedure for placing the prosthesis graft. Stent, in a broad sense, it is also understood by one of ordinary skill in the art that it is a prostheses to augment and impaired

blood vessel. D'Urso teaches a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60). Stent, in a broad sense, it is also understood by one of ordinary skill in the art that it is a prostheses to augment and impaired blood vessel. Therefore, it would have been obvious to employ these methods as disclosed by D'Urso to create the stent of Sirhan so that it too would have this advantage.

b. Applicant's arguments with respect to the rejection of claim 25 (see page 9 of the Remarks) have been fully considered but they are moot in view of new ground of rejection.

7. Applicant's arguments with respect to the rejection of claim 3, 11 and 12 (see page 9 of the Remarks) have been fully considered but they are not persuasive. Applicant argues that Eno et al. fails to disclose stent being customized to a patient and pre-formed having a sized and shape which morphologically matches the morphological profile and contour of the blood vessel, accordingly Eno do not cure the deficiencies of Sirhan or D'Uso. Sirhan as modified by D'Urso discloses all limitations in claims 3, 11, and 12 except for stent is in the form of a sleeve in at least two parts, the sleeve includes one or more sections of varying form. Since

the modified stent of Sirhan/D'Urso already has the characteristics of customized to a patient and pre-formed having a sized and shape which morphologically matches the morphological profile and contour of the blood vessel, therefore, Eno's sleeve that includes one or more sections of varying thickness to conform to the morphological profile of the connecting vessels and compliance with the pulsing of blood through the vessels (Eno, col. 3, line 22 to col. 4, line 16) will improve the effectiveness and utility of Sirhan/D'Urso device.

8. Referring to claim 34, Applicant argues that the Nakayama do not teach or suggest the method of manufacturing a stent by the steps of producing a 3D computerised model from a scanned image of the ascending aorta to which the stent is in practice to be applied, accordingly, Nakayama do not cure the deficiencies of D'Urso is incorrect. Noting that the limitation of "a scanned image of the ascending aorta" is not presented in claim 34. D'Urso teaches a method of manufacturing a stent for morphologically fitting a blood vessel (Fig. 5) by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60).

9. Referring to claims 32 and 35, applicant argues that D'Urso does not teach or suggest a method of manufacturing a stent for morphologically fitting a blood vessel of a patient to conform morphologically to the contour of the blood vessel

by providing a stent to support its exterior in essentially full contact there with is incorrect. D'Urso teaches a method of manufacturing a stent for morphologically fitting a blood vessel (Fig. 5) by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 1, 2, 4, 5, 6, 7-10, 20-22, 24-31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of D'Urso (US 6,112,109).**

13. Sirhan et al disclose (see Figs. 3, 10-16, 36-43 and 63) the invention substantially as claimed including a containment member 10 or stent, which is pre-formed before implanted into a patient, for locations exteriorly of a blood vessel, that can be formed in morphological relationship with a blood vessel, and means for maintaining the stent in relationship with the vessel (col. 7, lines 20-35 and col. 9, lines 35-45), forming the stent from a sleeve of at least two parts, the sleeve being generally of cylindrical form (col. 8, lines 54-65), the sleeve provided with appropriately located recesses or apertures for accommodating other interconnecting arteries (col. 11, lines 50-62), the interconnection of the parts of the sleeve effected by a hinge mechanism with releasable latches provided at the mating edges of the parts (col. 9, lines 35-42), wherein at least one spiral part is adapted in use to locate over and coil around the blood vessel to provide in position the morphological relationship with the blood vessel (col. 6, lines 2-4), and wherein each spiral part is provided with inter-engaging means for connection to an adjacent part (col. 7, lines 16-20) and the spiral forming an open coil or a closed coil around the blood vessel (col. 9, lines 1-12). Sirhan et al also disclose the inner surface of the stent to be of a smoothness to ensure that no fretting or abrasion occurs and the external surface of the stent is tolerant of other adjacent body parts (Figs. 14-16, the inside surface is shown to be smooth). Sirhan et al

further disclose that the material from which the stent is produced is resistant to the effects of electromagnetic fields (col. 6, lines 20-28; plastics are not electromagnetically sensitive), that the stent can be produced from a material that is thermally stable and biocompatible (col. 6, lines 20-28), and that the stent can be produced from any material that is composed of or a mixture of polymeric, metallic, or ceramic (col. 6, lines 20-28). Sirhan et al also disclose that the stent is adjustable in situ (col. 12, lines 4-10). Sirhan et al discloses the invention substantially as claimed except for the stent is customized.

14. However, D'Urso teaches a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5, lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36). Therefore it would have been obvious to employ these methods to create the stent of Sirhan so that it too would have this advantage.

15. Regarding **claim 5**, Sirhan et al further disclose that there is a base or flange portion adapted for attachment to a main heart structure such that a securement or anchor point is established for the stent, the base or flange portion being adapted for appropriate attachment to the said structure (col. 2, lines 50-56).

16. Regarding **claims 7-10**, Sirhan et al further disclose that the sleeve of the stent is slit longitudinally to allow it to be expanded over the wall of the artery and then to recover its original condition, the sleeve being suitably clampable in position embracing the artery in a morphological relationship (figs. 15A and 15B, notice how the sleeve edges overlap; the edges are created by a longitudinal slit), the clamping is achieved by the application of suitable ties and there are one or more grooves with the sleeve for receiving and locating the ties (col. 8, lines 25-30), and the clamping can be effected by the insertion of a locking pin extendable through hinge elements provided at the mating edges of the slit in the sleeve (col. 9, lines 35-42).

17. Regarding **claim 20**, Sirhan et al disclose that the material from which the stent is made from can be from polyethylene glycol material (col. 7, line 3). Noting that polyethylene glycol is a translucent material.

18. Regarding **claim 25**, as already established in the rejection of claim 1 above, Sirhan et al disclose the invention substantially as claimed but fail to disclose that the material from which the stent is made from can be a heat shrinks plastic material recoverable in terms of shape either immediately or over a period of time. Noting that Sirhan discloses the material is Nitinol. Examiner contends that Nitinol is old and well known in the art as a shape memory alloy, wherein the shape of the device that is made from Nitinol will be changed when the temperature is changed. Further, Examiner contends that shape memory polymer (SMP) is also old and well known in the art, wherein the shape of the device that is made from SMP will

be changed when the temperature is changed. It would have been obvious to one of ordinary skill in the art to replace Nitinol with a shape memory polymer because it has been held that substitution of one known element for another to obtain predictable results is old and well known in the art. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the material as claimed by the applicant, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

19. Regarding **claims 30 and 31**, D'Urso additionally teaches that a stent can be generated in the form substantially in which it is to be deployed in a surgical procedure (col. 5, lines 64-65) or that a precursor to the stent could be taken instead, in which case a mold would be taken of the precursor and then the stent formed in that mold (col. 5, lines 66-67).

20. Regarding **claim 36**, D'Urso teaches that these method steps are applicable to all types of implants, and does specifically include vascular implants (col. 9, lines 54-60) and can be used to make a stent as disclosed by Sirhan et al.

21. **Claims 3, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al (US 6,648,911) in view of D'Urso (US 6,112,109) further in view of Eno et al (US 6,197,050).**

22. As established in the rejection of claims 1 above, the modified device of Sirhan et al disclose the invention substantially as claimed except for the stent is in the form

of a sleeve in at least two parts, the sleeve includes one or more sections of varying form. However, Eno discloses a transmyocardial implant for establishing a blood flow path through a myocardium between a heart chamber and a lumen of a coronary vessel residing on an exterior of the heart (see Summary of The Invention) wherein the implant (see Fig. 3A) is a sleeve that includes one or more sections of varying thickness to conform to the morphological profile of the connecting vessels and compliance with the pulsing of blood through the vessels (col. 3, line 22 to col. 4, line 16). Therefore it would have been obvious to one of ordinary skill in the art to incorporate the design of the implant having varying thickness as disclosed by Eno into the modified device of Sirhan so that it too would have the same advantage.

23. **Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al in view of D'Urso as applied to claim 1 and 2 above and further in view of Doorly et al (US 6,554,856).**

24. The modified device of Sirhan et al disclose the invention substantially as claimed except for the sleeve has an outer and inner casing wherein the outer casing is of more rigid construction that the inner casing and wherein the inner casing is of petal-like form. However, Doorly et al teach (Fig. 2) an outer and inner casing wherein the outer casing is of more rigid construction that the inner casing and wherein the inner casing is of petal-like form 2 (col. 3, lines 56-59). Apparently varying the flexibility of the stent in this manner allows it to have a better conforming capability to achieve a better morphological fit between the implant

and vessel. Therefore it would have been obvious to have the inner and outer casings of different rigidities and to have petal like forms to allow a better morphological fit between the stent and vessel.

25. **Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (US 6,112,109) in view of Nakayama et al (US 2006/0036311).**

26. D'Urso discloses the method substantially as claimed including a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5, lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36). D'Urso fails to disclose that the shell of the stent is machined to provide perforations. However, Nakayama teaches a method wherein the shell is mounted in a computer numerically controlled machine having multiple axes control and is machined to provide appropriate perforations to accommodate the subsidiary blood vessels (par. 93 and claim 22). Machining the perforations allows precise control in the manufacturing process so that the perforations in the stent align correctly with the subsidiary blood vessels, thus providing a morphologically correct fit. Since it has been held use of known technique to a known device ready for improvement to yield predictable results is old and well

known in the art, therefore it would have been obvious to one of ordinary skill in the art to use the method of making the perforations in a stent as disclosed by Nakayama to make the device of D'Urso.

27. **Claims 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso (US 6,112,109) in view of Phillips et al (US 6,899,728).**

28. D'Urso discloses the method substantially as claimed including a method of manufacturing a stent for morphologically fitting a blood vessel by the steps of producing a 3D computerized model from a scanned image of the blood vessel and rapid prototyping the computerized 3D model in an appropriate material to provide the stent or a mold for the stent or a precursor thereof for morphologically matching the blood vessel (col. 6, lines 33-54 and col. 9, lines 48-60), that the scanned image is obtained by either MRI, MRA, X-ray CT, or 3D pulsed Doppler (col. 5, lines 34-36), and that the computerized 3D model is generated by using CAD (col. 5, lines 30-36). D'Urso fails to disclose that the stent is produced by embroidering the 3D image onto at least one 2D substrate element. However, Phillips discloses a method of embroidering a reinforcing wire on a 2D substrate element and the substrate is subsequently rolled into to tubular shape (see Abstract and Entire reference). Apparently the reinforcing wire provides the stent from collapsing. Since it has been held use of known technique to a known device ready for improvement to yield predictable results is old and well known in the art, therefore it would have been obvious to one of ordinary skill in the art to use the

method of embroidering a reinforcing wire to the stent as disclosed by Phillips to make the device of D'Urso so that it too would have the same advantage.

Allowable Subject Matter

29. Claim 33 is allowable over prior art of record. No combinations of the prior art disclose or fairly suggest all of the limitation of this claim, particularly the steps of embroidering a woven structure onto shell, especially, the step of removing the shell following completion of the embroidery to provide a stent.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Harrison et al (US 5,573,776) discloses polyethylene glycol is translucent (col. 20, line 25-30). Langer et al. (US 6,160,084) disclose shape memory polymer is old and well known in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Tuan V Nguyen/

Examiner, Art Unit 3731